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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/924,540	Applicant(s) JAYARAMAN, SWAMINATHAN	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-19,26,31-35,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-19,26,31-35,37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgement is made of the request for continued application, amendment and remarks, all dated 2-17-04.

Claims 3-19, 26, 31-35, 37 and 38 are present for prosecution. Claims 3-7, 9-11, 14-19, 26, and 37 have been amended. Claims 1, 2, 20-25, 27-30, and 36 have been canceled.

Claim Rejections - 35 USC § 112

Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claim 37 recites medicinal agents selected from the group consisting of a pharmaceutical active, a supplemental nutrient, a beneficial agent and a combination thereof, which are further limited, in the dependent claims, to various groups of pharmaceutical agents such as anti-neoplastic agents, anti-depressants, an autonomic drug etc., supplemental nutrients such as fermentable or non-fermentable dietary fiber, oligosaccharide, phytochemical, pyruvate precursor etc., and beneficial agents such as probiotic, an enzyme, a diagnostic agent etc.

However, besides mentioning aspirin and sildenafil citrate, does not describe or exemplify any specific drug or an enzyme or a phytochemical or probiotic or a diagnostic agent that could suitably be employed in the instant filter bag. Accordingly, a mere listing of a pharmaceuticals or beneficial agents by their function does not provide adequate written description as it does not clearly and concisely convey to one skilled in the art that inventors, at the time of the instant was filed, was in possession of the claimed invention.

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Claims 3-19, 26, 31-35 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a filter bag coated with aspirin or sildenafil citrate, does not reasonably provide enablement for a filter bag coated with any pharmaceutical, beneficial agent or a supplemental nutrient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “*undue*”. See *In re Wands*, 858 F.2d 731, 737, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1998). The court set forth the eight factors to consider when assessing if a disclosure would require undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546, the court recited eight factors

The breadth of the claims and the nature of the invention: The claims are drawn to filter bag for oral administration of medicament comprising at least one sheet of porous material having a therapeutically effective amount of at least one medicinal agent selected from a pharmaceutical active, a supplemental nutrient, a beneficial agent and a combination thereof. The pharmaceutical active is selected from a variety of therapeutics (recited in claim 3) or a supplemental nutrient (claim 4) or a beneficial agent (claim 5), which are mainly described by their function.

The state of the prior art and predictability: The art teaches filter bag materials for oral administration such as tea bags, coffee bags, and beverage bags. The art also teaches administering medicaments for therapeutic purposes by adding a desired medicament to

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the tea leaves present inside the bag and upon brewing the medicament is released into water along with tea extract and is consumed by the subject in need of the medication (JP 10137321 A). As applicants admit, the herbal tea product included in the teabags has been conventionally used for treating several ailments. Further, the prior art also recognizes coating the bag covering the enclosed tea leaves with materials such as starch so as to preserve the flavor and aroma of the enclosed tea (JP 53075346 A2). Prior art (US 5,921,955) teaches incorporating a beneficial agent in a retention pocket to hold one or more beneficial agents. However, the art does not recognize incorporating probiotics, diagnostic agents or autonomic drugs, chemotherapeutic or anti-neoplastic agents etc., in the filter bags.

(6-7) The amount of direction provided by the inventors and the existence of working

examples: Applicants have described in the instant specification that a number of beneficial agents, pharmaceutical actives or nutrient supplements can be introduced in the bag material of the instant product. Applicants also state that the medicament is never mixed with the beverage inside the bag and is coated or incorporated in the bag material such that the medicament is soluble upon contact with liquids and accordingly is ingested in proper dosage upon administration. However, instant specification provides no guidance as to how to prepare the medicament such that it is incorporated in the bag material i.e., as a powder or solubilized and applied a liquid coating etc. Further it is not mentioned if all of the materials claimed i.e., drugs or nutrients or other beneficial agents, are soluble upon contact with liquid, or any mechanism as to how the medicaments claimed are released. Applicants only mention aspirin and sildenafil citrate, but fails to

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state any particular compound that falls in the other categories such as probiotics, autonomic drug, chemotherapeutic drugs, which are generally known to be insoluble in water.

(8) The quantity of experimentation needed to make or use the invention bases on the content of the disclosure:

As mentioned, instant specification fails to provide any guidance in the form of description, examples, figures or other, as to how to apply a medicament to the porous sheet of the claimed filter bag. Applicants refer to US patent No. 5,871,789, incorporated by reference, for making tea bags. However, the cited patent only teaches preparing tea bags but does not teach or suggest as to how to incorporated any of the vast number of the known medicaments in the art. Furthermore, instant claimed agents such as autonomic drug, phytochemical, oligosaccharide, mineral, pyruvate precursor, probiotic, diagnostic agent etc., are broad and includes besides those compounds that have not yet been identified to have such as function and may include compounds having different functional properties. Applicants fail to provide any guidance as to what kind of diagnostic agent, for diagnosing what type of condition etc. Accordingly, in the absence of any guidance from the instant specification, one of an ordinary skill in the art would have to perform undue experimentation in order to identify or choose the right compound that belongs to the claimed categories, chose the amount to be incorporated, prepare an appropriate liquid or solid or a powder or other suitable form of the compound so as to apply to the filter bag and finally in the process of application of the medicament i.e., mix with the porous sheet material before forming the sheet, apply to the sheet material by

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affixing or spraying the medicament, sprinkle the medicament or dip the paper into medicament solution etc. Thus further testing would be necessary to use the claimed invention and the practice of the full scope of the invention would require undue experimentation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 18, 19, 26, 34, 35 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1603414 (hereafter GB).

GB discloses a tea bag made from a water-pervious (reads on instant porous sheet) material having an edible acidic material incorporated therein, and the water used for infusing tea bag liberates the acidic material from the sheet into the liquor, leading to the desired color improvement (page 1, lines 30-40). GB further teaches that the teabag encloses tealeaves and thus GB meet the claim requirement that the medicinal agent is not directly mixed with the tealeaves of claims 26 and 37. Instant claim 37 recites a therapeutically amount of at least one medicinal agent and further defines that the medicinal agent includes a beneficial agent. Because the acidic material imparts the benefit of imparting color and flavor to tea, it is examiner's position that GB meets claim requirements. With respect to claims 6-8, GB teaches that the acidic material is released into the liquid or water and acid is soluble. GB discloses various materials suitable for making the bag that includes paper or fabric or gauze (page 2, lines 22-28)

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and hence meets the requirement of claims 18 and 34. With respect to claims 19 and 35, GB discloses enclosing tealeaves inside the bag (page 1). Thus, GB anticipates instant claims.

Claim Rejections - 35 USC § 103

Claims 3-5, 9 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of JP 09108111 (JP '111) and GB 1603414 (hereafter GB).

OR

Claims 3-5, 9 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of GB and JP '111 in view of CN 1104036.

GB teaches a teabag enclosing tealeaves and the tea bag material incorporated with an acidic material that releases acid upon contact with water and thus enhances the color and flavor of tea. GB teaches incorporating acids such as citric, tartaric, malic etc., but does not specify the claimed medicament or groups of medicaments, in the bag paper.

JP '111 teaches teabag comprising two filtration layers of Japanese paper or synthetic resin, wherein both the layers hold tealeaves in the inner side. The filtration bag reads on the porous sheet of the instant claim. JP '111 teaches varieties of tealeaves including green tea, oolong tea, water chestnut, safflower etc., all of which are herbs and thus read on the instant medicines. JP '111 also teaches a shelf fungus that reads on the claimed probiotic. JP '111 further teaches green tea, oolong tea etc. Oolong tea is known for its medicinal value.

Alternatively, CN 1140306 teaches oolong tea preparation for treating gastric and duodenal ulcers, thus suggesting the medicinal value of oolong tea.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the oolong tea or any other agent having medicinal value (of JP '111) and apply

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tea as coating on the porous sheet material that forms the tea bag because GB suggests applying a desired material such a color imparting or flavor imparting material in the sheet material such that the dosing problem is mitigated and also a better control on the release of the desired material is achieved. Accordingly, one of an ordinary skill in the art would have expected to readily release the desired amount of a medicinal agent into the tea preparation upon contacting the tea bag with water and thus be able to provide desired treatment.

Claims 10-17 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of JP 09108111 (JP '111) and GB 1603414 (hereafter GB) as applied to claims 3-5, 9-11 and 38 above, and further in view of JP 53075346 (Mori et al)

OR

Claims 10-17 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over a combination of JP 09108111 (JP '111) and GB 1603414 (hereafter GB) in view of CN 1104036 as applied to claims 3-5, 9-11 and 38 above, and further in view of JP 53075346 (Mori et al).

GB discussed above teaches teabag coated with color and flavor improving acid materials and enclosing tealeaves inside the teabag. GB fails to teach a drug-releasing element in the teabag. JP '111 also fails to teach a drug-releasing element, claimed in the instant claims.

Mori et al teach a flavor preserving tea bag, comprising a coating over the tea bag paper. The compounds suitable for coating comprise amylose starch, cellulose derivatives, alginates, gelatin etc. Mori et al teach the coating does not affect the aroma, flavor or taste of the tea. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the

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instant invention use a gelatin material or other cellulose or starch materials as a film on the tea bag which still is able to release the tea extract upon contact with water because Mori suggests that gelatin acts as a material to provide a prolonged shelf life. While Mori does not state that gelatin is a drug releasing material, instant claims are directed to a product and not to a method of releasing a drug. Accordingly, gelatin material taught by Mori also possesses the properties or characteristics of drug relelasing element and hence meets the claim requirements.

Response to Arguments


Applicant's arguments with respect to claims 3-19, 26, 31-35 and 37 have been considered but are moot in view of the new ground(s) of rejection.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615
May 15, 2004